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EXAMINER	
TREYGER, ILYA Y	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,945	AXELSSON ET AL.	
	Examiner	Art Unit	
	ILYA Y. TREYGER	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/11/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The rejection of claims 1-6, 8-10, 12, 13, 15, 18, 19, 21, and 23-32 under 35 U.S.C. 112, first paragraph has been withdrawn in view of the amendment made to the claims.

2. Claims 1-6, 8-10, 12, 13, 15, 18, 19, 21, and 23-32 are amended.

3. Claims 36-44 are canceled.

4. Claims 1-35 of are examined on the merits.

Response to Arguments

5. Applicant's arguments filed 02/04/2009 have been fully considered but they are not persuasive:

6. With regards to claim 1, Applicants argue that the combination of Dadson and Lee does not disclose the claimed invention because the clip of Lee may prevent crossing of the flexible tubing at the clip, but Lee does not teach, disclose, or suggest a package where no part of the line set extends across another part of the line set, and the Examiner has not shown anywhere in the prior art, the teaching of a package "organizing means" where "no part of the line set extends across another part of the line set", as recited in independent claim 1.

However, the clip of Lee defines the disposition of the tube elements within the same plane that provides the condition of reciprocal non-crossing of the tubular elements, and therefore the clip of Lee is fully capable of being arranged to organize the line set such that no part of the line set extends across another part of the line set (See Figs. 7-10).

7. Applicants further argue that neither Dadson nor Lee suggest, teach, or disclose a "package including the line set [that] is configured to substantially eliminate damage to the package or line set related to sterilization.

Applicants set forth the manner in which the claimed apparatus operates. However, a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Since the combination of references discloses substantially the same structure, as that claimed by applicant, the structure is fully capable of performing the claimed function.

8. With respect to claim 27, Applicants argue that neither Dadson nor Lee disclose, teach, or suggest "the step of organizing the line set within the package such that no art of the line set extends across another part of the line set during sterilization of the package", as recited in independent claim 27.

However, since the clip of Lee defines the disposition of the tube elements within the same plane that provides the condition of reciprocal non-crossing of the tubular elements, the step of organizing the line set such that no part of the line set extends across another part of the line set and fully capable of being arranged to organize the line set such that no part of the line set extends across another part of the line set is disclosed (See Figs. 7-10).

9. Applicants further argue that Lee teaches away from Applicant's invention because Lee teaches use of its device during hospital treatment and not during sterilization.

However, the use of the device during the hospital treatment does not preclude for use the device during the sterilization. Moreover, the teaching of use the device during the sterilization

lies in the fact that the use of the sterilized devices is the mandatory requirement of any hospital invasion procedures.

10. With respect to claims 5, 13-17, 20, 30-33 and 35, Applicant's arguments are substantially identical to arguments discussed in paragraphs 6-9 above.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-4, 6-12, 18, 19, 21-26, 27, 19, 31, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885).

13. In Re claim 1, Dadson discloses a device for use in a peritoneal dialysis treatment (Abstract, line 1), wherein the package (Col. 5, line 61) includes a line set fully capable of being non-sterile which comprises a first tubular line element 54 fully capable of being non-sterile, a second tubular line element 52 fully capable of being non-sterile, and elements 60, 61, 65, 69 fully capable of being non-sterile connected to the tubular line elements 54 and 52 (See Fig. 1) fully capable of being non-sterile, wherein the package is configured to substantially eliminate the risk of damage to the package or line set during sterilization, since the line set has been disclosed as supplied in sterile condition in a single PD package (Col. 5, lines 64, 65).

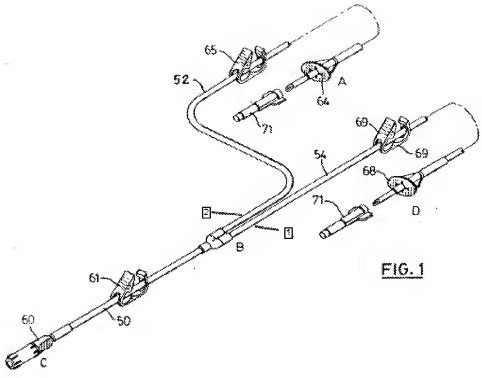
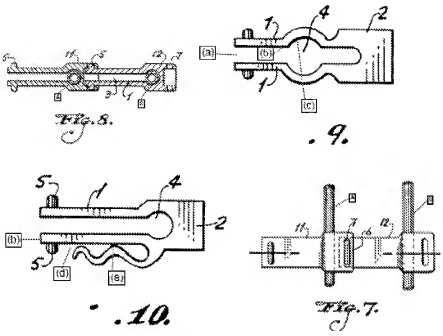


FIG. 1

Dadson does not expressly disclose the organizing means connected to both first and second tubular elements and arranged to organize the line set such that no part of the line set extends across another part of the line set.

Lee teaches that it is known to use an organizing means connected to both first A and second B tubular elements. Since the clip of Lee defines the disposition of the tube elements within the same plane, it is fully capable of being arranged to organize the line set such that no part of the line set extends across another part of the line set (See Figs. 7-10).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with an organizing means, as taught by Lee because such modification would provide the organizing of the tubing package for use in a peritoneal dialysis treatment in the safety mode.

In response to the limitation "during sterilization", Applicants set forth the manner in which the claimed apparatus operates. However, a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Since the combination of references discloses substantially the same structure, as that claimed by applicant, the structure is fully capable of performing the claimed function.

14. In Re claim 2, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means is arranged to organize the whole line set at substantially the same level.

Lee teaches that it is known to make the organizing means arranged to organize the whole line set fully capable of being non-sterile at substantially the same level (See Figs. 7-10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with an organizing means, as taught by Lee because such modification would provide a set being portable.

15. In Re claim 3, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means arranged to organize the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements.

Lee teaches that it is known to make the organizing means fully capable of being arranged to organize the line set fully capable of being non-sterile such that no part of the first and second tubular line elements is in contact with another part of the first and second tubular line elements (See Figs. 8, 9, and 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with the organizing means arranged to organize the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements, as taught by Lee because such modification would prevent tubing from the mechanical damage during the storing the package.

16. In Re claim 4, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means arranged to organize the line set in a spiral-shaped state.

Lee teaches the organizing means fully capable of being arranged to organize the line set fully capable of being non-sterile in a spiral-shaped state (See Figs. 7 and 8).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with the organizing means arranged to organize the line set in a spiral-shaped state, as taught by Lee in order to make the package portable.

17. In Re claim 6, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means comprising the holding member configured to hold at least one portion of the first tubular line element in a predetermined position in relation to a portion of the second tubular line element.

Lee teaches the organizing means comprising the holding member configured to hold at least one portion of the first tubular line element A in a predetermined position in relation to a portion of the second tubular line element B fully capable of being non-sterile (See Figs. 7 and 8).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with the organizing means comprising the holding member, as taught by Lee in order to prevent unpredictable moving of the tubing elements.

18. In Re claim 7, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means comprising the holding member arranged to perform said holding in a detachable manner.

Lee teaches the organizing means comprising the holding member performing the holding in a detachable manner.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with the organizing means comprising the holder arranged to organize the line set in a detachable manner, as taught by Lee in order to simplify operation the device.

19. In Re claim 8, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means comprising the holding member further comprising a first elongated recess, restricted by at least one resilient jaw-shaped member, said resilient jaw-shaped member being provided with at least one concavity for holding detachable said portion of the first tubular line element.

Lee teaches the organizing means comprising the holding member further comprising a first elongated recess (a), restricted by the resilient (Col. 3, ln. 47) jaw-shaped member (b) being provided with the concavity (c) for holding detachable the portion of the tubular member (See Fig. 9) fully capable of being non-sterile.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson with the organizing means comprising the holding member further comprising a first elongated recess, restricted by the resilient jaw-shaped member being provided with the concavity for holding detachable the portion of the tubular member, as taught by Lee in order to improve the reliability of the holding the tubular element by the holding member.

20. In Re claim 9, Dadson discloses the claimed invention discussed above, as applied to claim 6 above, but does not disclose the organizing means wherein the holding member is configured to hold at least one portion of the first tubular line element and the at least one portion of the second tubular line element, said at least one portion of the first tubular line element and said at least one portion of the second tubular line element being configured in a predetermined position in relation to each other, such that the first and second tubular line elements have a substantially parallel extension in the vicinity of the holding member.

Lee teaches the organizing means wherein the holding member is configured to hold at least one portion of the first tubular line element A fully capable of being non-sterile and at least one portion of the second tubular line element B fully capable of being non-sterile, said at least one portion of the first tubular line element and said at least one portion of the second tubular line element being configured in a predetermined position in relation to each other, such that the first and second tubular line elements fully capable of being non-sterile have a substantially parallel extension in the vicinity of the holding member (See Fig. 7).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of holding member configured to hold at least one portion of the first tubular line element and the at least one portion of the second tubular line element, said at least one portion of the first tubular line element and said at least one portion of the second tubular line element being configured in a predetermined position in relation to each other, such that the first and second tubular line elements have a substantially parallel extension in the vicinity of the holding member. It would have been obvious to one having ordinary skill in the art at

the time the invention was made to employ the holding member of Lee to the device of Dadson in order to provide device with the type of holding member that is known to be suitable for holding tubular elements in a predetermined position substantially parallel to each other.

21. In Re claim 10, Dadson discloses the claimed invention discussed above, as applied to claim 7, but does not disclose the organizing means wherein the holding member is configured to hold fixedly a second connector, said second connector being mounted to an end of the second tubular line element.

Lee teaches the organizing means wherein the holding member is fully capable to hold fixedly a connector being mounted to an end of the second tubular line element fully capable of being non-sterile, since the organizing means can comprise the unlimited quantity of clips (holding members) comprising the concavity (c) for holding detachable the portion of the tubular member (See Figs. 7-10).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of holding member configured to hold fixedly a connector being mounted to an end of the tubular line element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the holding member of Lee to the device of Dadson in order to provide device with the type of holding member that is known to be suitable for holding fixedly a connector being mounted to an end of the tubular line element.

22. In Re claim 11, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means wherein the holding member comprises a hole extending through the holding member for receiving said connector.

Lee teaches the organizing means wherein the holding member comprises a pocket 4, which is a variation of the hole, and fully capable of receiving the connector mounted to the end of the tubular line element (See Figs. 8-10).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of the holding member comprising the hole for receiving the connector mounted to the end of the tubular line element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the holding member of Lee to the device of Dadson in order to provide the device with the type of holding member that is known to be suitable for holding the connector mounted to the end of the butulare line element.

23. In Re claim 12, Dadson discloses the line set comprising a drain bag, and the line set, fully capable of being non-sterile, is connected to the drain bag (See Col. 6, ln. 14).

24. In Re claim 18, Dadson discloses the package wherein the package comprises a drain bag and the line set, fully capable of being non-sterile, is connected to the drain bag via connector 68 positioned at an outer periphery of the line set (See Col. 6, ln. 7-9; Fig. 1).

25. In Re claim 19, Dadson discloses the package wherein the package comprises a solution bag and the line set, fully capable of being non-sterile, is connected to the solution bag (Col. 6, ln. 60, 61; Col. 7, ln. 16-18).

26. In Re claim 21, Dadson discloses the package wherein the line set, fully capable of being non-sterile, is connected to the solution bag via connector 64 positioned at an outer periphery of the line set (See Col. 6, ln. 7-9; Fig. 1).

27. In Re claim 22, Dadson discloses the package wherein the solution bag is filled with a dialysate solution (Col. 6, ln. 60, 61).

28. In Re claim 23, Dadson discloses the package wherein the line set, fully capable of being non-sterile, comprises a third connector 60 connectable to a patient connector (See Col. 6, ln. 3-5; Fig. 1).

29. In Re claim 24, Dadson discloses the package wherein the third connector 60 is configured in a space at an inner periphery of the line set (See Fig. 1) fully capable of being non-sterile.

30. In Re claim 25, Dadson discloses the package wherein the line set, fully capable of being non-sterile, comprises a component in the form of at least one flow organizer 65, 68 (Fig. 1) fully capable of being arranged to provide a space sufficient for the flow organizer such that the flow organizer does not load on any part of the first and second tubular line elements.

31. In Re claim 26, Dadson discloses the package wherein the package comprises a wrapping for encasing the line set (Col. 5, ln.61, 62), fully capable of being non-sterile, since in accordance with the definition the package is "a wrapped or boxed object" (See The American Heritage® Dictionary of the English Language, Fourth Edition), what reads on comprises a wrapping.

32. In Re claim 27, Dadson discloses a method for manufacturing of a package for use in a peritoneal dialysis treatment (Abstract, line 1), wherein the package (Col. 5, line 61) includes a line set fully capable of being non-sterile which comprises a first tubular line element 54 fully

capable of being non-sterile, a second tubular line element 52 fully capable of being non-sterile, and elements 60, 61, 65, 69 fully capable of being non-sterile connected to the tubular line elements 54 and 52 (See Fig. 1) fully capable of being non-sterile, wherein the package is configured to substantially eliminate the risk of damage to the package or line set during sterilization, since the line set has been disclosed as supplied in terile condition in a single PD package (Col. 5, lines 64, 65).

Dadson does not expressly disclose the organizing means connected to both first and second tubular elements and arranged to organize the line set such that no part of the line set extends across another part of the line set.

Lee teaches that it is known to use an organizing means connected to both first A and second B tubular elements. Since the clip of Lee defines the disposition of the tube elements within the same plane (See Figs. 7-10), the step of organizing the line set such that no part of the line set extends across another part of the line set and fully capable of being arranged to organize the line set such that no part of the line set extends across another part of the line set is disclosed (See Figs. 7-10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with an organizing means, as taught by Lee because such modification would provide the organizing of the tubing package for use in a peritoneal dialysis treatment in the safety mode.

33. In Re claim 29, Dadson discloses the claimed invention discussed above, but does not expressly disclose the method characterized by the step of organizing the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements.

Lee teaches that it is known to use the organizing means capable to organize the line set, fully capable of being non-sterile, such that no part of the tubular line elements, fully capable of being non-sterile, is in contact with another part of the tubular line elements (See Figs. 8, 9, and 10), fully capable of being non-sterile.

Since the organizing means capable to organize the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Dadson with the step of organizing the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements, as taught by Lee because such modification would prevent tubing from the mechanical damage during the storing the package.

34. In Re claim 31, Dadson discloses the claimed invention discussed above, but does not expressly disclose the method including the step of organizing the line set by means of a holding member being configured to hold at least one portion of the first tubular line element in a predetermined position, in relation to a portion of the second tubular line element.

Lee teaches the organizing means comprising the holding member configured to hold at least one portion of the first tubular line element A, fully capable of being non-sterile, in a predetermined position in relation to a portion of the second tubular line element B (See Figs. 7 and 8), fully capable of being non-sterile.

Since the organizing means capable to hold one portion of the tubular line element in a predetermined position in relation to another tubular line element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of

Dadson with the step of organizing the line set by means of a holding member being configured to hold at least one portion of the first tubular line element in a predetermined position, in relation to a portion of the second tubular line element, as taught by Lee in order to prevent unpredictable moving of the tubing elements.

35. In Re claim 34, Dadson discloses the package wherein the package comprises a wrapping for encasing the line set (Col. 5, ln.61, 62), since in accordance with the definition the package is "a wrapped or boxed object" (See The American Heritage® Dictionary of the English Language, Fourth Edition), what reads on comprises a wrapping.

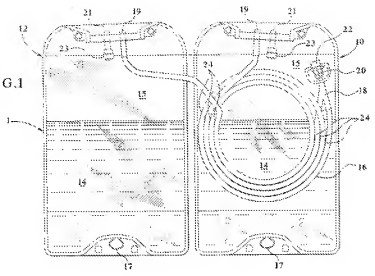
Since the package comprising the wrapping disclosed as provided, it means the step of providing the package with a wrapping has been disclosed.

36. Claims 5, 13, 15-17, 20, 30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885) and further in view of Keilman (US 5,820,582).

37. In Re claim 5, Dadson in view of Lee disclose the claimed invention, as applied to claim 1 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein at least one tubular lane element is pre-shaped to extend along a desired path.

Keilman teaches the system used for a peritoneal dialysis procedure (See Abstract, ln. 4, 5), wherein tubular lane elements, fully capable of being non-sterile, are pre-shaped to extend along a desired path (See Fig. 1).

FIG.1



All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of tubing packaged in the pre-shaped form. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the tubing packaged in the pre-shaped form of Keilman to the device of Dadson/ Lee in order to provide device with the tubing packaged in the pre-shaped form.

38. In Re claim 13, Dadson in view of Lee disclose the claimed invention, as applied to claim 1 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the first and second tubular line elements, are manufactured of PVC.

Keilman teaches the system used for a peritoneal dialysis procedure (See Abstract, ln. 4, 5), wherein tubular line elements, fully capable of being non-sterile, are manufactured of PVC (See Col. 6, ln. 30-32).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the

predictable result of tubing for dialysis procedure made of PVC. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the PVC tubing of Keilman to the device of Dadson/ Lee in order to provide device with the tubing made of material that is known to be suitable for tubing set used for dialysis procedure.

39. In Re claim 15, Dadson in view of Lee disclose the claimed invention, as applied to claim 12 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the drain bag is foldable to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag.

Keilman teaches the drain bag constructed of flexible plastic material (Col. 2, ln. 19, 20) and, consequently, fully capable of being folded in the claimed manner.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee with the flexible bag foldable to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag, as taught by Keilman in order to make the package portable.

40. In Re claims 16 and 17, Dadson in view of Lee and further in view of Keilman disclose the claimed invention, , but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the holding member is arranged to detachably engage one of said first and second folded parts of the drain bag, and wherein the holding member comprises a second recess restricted by at least one resilient jaw-shaped member, said jaw-shaped member is provided with at least one protruding member for engaging detachably the edge area.

Lee teaches the holding member comprising the recess (d) restricted by the resilient jaw-shaped member (b), and protruding member (e) (See Fig. 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee / Keilman with the holding member, as taught by Keilman, since Keilman discloses substantially the same structure, as that claimed by applicant, the structure is fully capable of performing the claimed function of the holding member being arranged to detachably engage the folded part of the drain bag.

41. In Re claim 20, Dadson in view of Lee disclose the claimed invention, as applied to claim 12 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the drain bag is applied on the solution bag.

Keilman teaches the system, wherein the drain bag is applied on the solution bag (See Col. 2, ln. 3, 10-13; Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee with the drain bag is applied on the solution bag, as taught by Keilman in order to form the package is such a manner to substantially reduce packaging size requirements and to simplify the packaging procedure.

42. In Re claim 30, Dadson in view of Lee disclose the claimed invention, as applied to claim 27 above, but do not expressly disclose the method for use in a peritoneal dialysis treatment, including the step of organizing the line set in a spiral shaped state.

Keilman teaches the line set, fully capable of being non-sterile, provided in a spiral shaped state (See Fig. 1).

Since the line set organized in a spiral shaped state has been disclosed as provided, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Dadson/ Lee with the step of organizing the line set in a spiral shaped state, as taught by Keilman because such modification would provide the compact packaging of the line set.

43. In Re claim 32, Dadson in view of Lee disclose the claimed invention, as applied to claim 27 above, but do not expressly disclose the method, the steps of folding the drain bag to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag.

Keilman teaches the drain bag constructed of flexible plastic material (Col. 2, ln. 19, 20) and, consequently, fully capable of being folded in the claimed manner.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Dadson/ Lee with the steps of folding the drain bag to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag, as taught by Keilman in order to make the package portable.

44. In Re claim 33, Dadson in view of Lee disclose the claimed invention, but do not expressly disclose the method including the step of applying the drain bag on the solution bag.

Keilman teaches the system, wherein the drain bag is applied on the solution bag (See Col. 2, ln. 3, 10-13; Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Dadson/ Lee with the step of applying the drain

bag on the solution bag, as taught by Keilman in order to form the package is such a manner to substantially reduce packaging size requirements and to simplify the packaging procedure.

45. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885), as applied to claim 12 above, and further in view of Maasola (US 4,772,497).

Dadson in view of Lee disclose the claimed invention discussed above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the drain bag is manufactured of a plastic material having higher resistance against heat than PVC.

Maasola teaches the bag for medical solutions made of a mixture of polyolefin and an elastomer (See Abstract, ln. 9-12). Since the bag material of Maasola is substantially identical to the bag material of claim 14 by its chemical composition (See Specification, page 4, [0034], ln. 27-30), the resistance against heat is inherent, as per In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee with the drain bag manufactured of a plastic material having higher resistance against heat than PVC, as taught by Lee in order to make the bag compatible with the steam sterilization precess.

46. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885), as applied to claim 27 above, and further in view of Shang et al. (US 2002/0115795).

Dadson in view of Lee disclose the claimed invention discussed above, but do not expressly disclose the method including the step of exposing the package for autoclave sterilization.

Shang teaches the step of placing (exposing) the tube set in a steam autoclave.

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of the autoclave sterilization process. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Dadson/ Lee with the step of placing (exposing) the tube set in a steam autoclave, of Shang in order to provide the method with the sterilization process known in the art.

Conclusion

47. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Y Treyger/
Examiner, Art Unit 3761

/Michele Kidwell/
Primary Examiner, Art Unit 3761